Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13265

1 - AFFIDAVITS

AFFIDAVIT

SAMPLE NO. 48053

STATE OF [redacted]

COUNTY OF [redacted]

Before me, Renee L. Rice, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-98, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared [redacted] in the county and State aforesaid, who, being duly sworn, deposes and says:

I am Mrs [redacted] and I reside at [redacted]

On 09/07/98, I purchased one bottle of Metabolife Dietary Supplement 356 (90-caplet bottle, distributed by Metabolife International Inc.) from a retail stand located in [redacted] so that I would lose weight. On the same day, I took a half a caplet and I felt very energetic. I continued taking a half of a caplet for the next couple of days and then took 2-3 caplets a day for approximately three weeks.

After about two weeks of taking the product, I noticed a small lump in my abdomen which was about the size of a tennis ball. Around the third week, I noticed that the lump had ~~doubled~~ reached to about the size of a large cantelope J.W. I felt abdominal bloating but I was not in pain. At this time, I discontinued taking the product.

On 10/7/98, I went to [redacted] because I felt the lump in my abdomen was continuing to grow in size. The physician on duty (i.e., Dr. [redacted] performed several tests and I was released that day. Dr. [redacted] told me that I had an enlarged mass in my abdomen and to schedule a follow-up visit to see her again.

On 10/9/98, I visited Dr. [redacted] at the [redacted] The physician performed several tests and surgery was scheduled for 01/19/99 to remove the tumor mass located on my left ovary.

On 10/19/98, I was hospitalized at [redacted] and Dr. [redacted] removed both the benign tumor mass and my left ovary. The physician also told me that she observed a small ruptured cyst on my right ovary while performing the surgery. I was released from the hospital on 10/21/98.

On 11/17/98, my husband [redacted] reported my incident (mentioned above) to the U.S. Food and Drug Administration located in Detroit, MI. FDA Investigator Rice informed me that this was reported as a Complaint/Injury Report (DET-0789) which generated a CFSAN Medwatch assignment #13265.

On 02/01/99, FDA Investigator Rice visited my home and I discussed this incident and allowed her to take pictures of the product.

On 03/05/99, FDA Investigator Renee L. Rice took photographs and provided me with my medical records pertaining to this event. FDA Investigator Rice collected from me 25 caplets of the Metabolife Dietary Supplement 356 and provided me with the receipt for the sample.

I also provided Investigator Rice with my medical records [redacted]

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AFFIANT'S SIGNATURE AND TITLE [redacted]

FIRM'S NAME AND ADDRESS *(Include ZIP Code)* [redacted]

Subscribed and sworn to before me at [redacted] this 5 day of March, 1999.

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Renee L. Rice

*(Employee's Signature)*

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

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COMPLAINT/INJURY F/U DET-0789
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